fall within the scope of the prior art compositions, would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the instant invention was made. [Page 2 of the Office Action]

The rejection is traversed in respect of anticipation on the basis that the WO published application (hereinafter Kornman) does not disclose any formulation for topical application to the eye of an animal. No formulation disclosed in Kornman is suitable for topical application to the eye. For instance, Example 1 discloses a composition which is applied by syringing, and Example IV discloses a topical composition, a mouthwash, containing components such as ethanol, which is an irritant and certainly unsuitable for use in an eye formulation.

Nor does the disclosure of Kornman render Applicant's invention obvious. It in fact leads away from topical compositions by virtue of disclosing components which are irritating or out-and-out harmful to the eye.

The disclosure in Kornman starting at page 6, line 28 discloses "fluid gel or paste-like compositions", and appears to be the disclosure which served as a basis for the Examiner's comments on Kornman's disclosure of a gel. The compositions described by Kornman in the section cited by the Examiner are not suitable as topical compositions for the eye, however, and Kornman does not describe them as such. Rather, read in context, these compositions are sustained release oral drug delivery systems which transform into a near solid (page 6 line 7). They are described as able to be "....used advantageously when desired from a syringe-like apparatus", and thus it seems they would more properly be classed as injectables (see Example I which describes such a composition as being injected with a syringe). Kornman also discloses that his gels may use bioerodible polymers, such as polylactic acid, polyglycolic acid, and polylactyl-co-glycolic acid. Solidifying gels comprising the PLGA copolymers disclosed by Kornman, however, contain high concentrations of organic solvents, such as N-methyl pyrrolidone, ethanol, propylene glycol, and triacetin, that are toxic and deleterious if applied to the eye. Furthermore, these polymers degrade to lactic and glycolic acids, which can lower the pH of the tear film and cause

toleration problems. In any event, Kornman's gel composition is clearly described as being a syringeable composition for administration to pockets in the oral cavity where they form solids. The Office has provided no basis otherwise that such a gel/solid composition is a composition for topical application to an eye, as required by all claims which stand rejected.

To the extent any **topical** compositions are described in Kornman, they are disclosed (i.e., specifically as being "topical") starting at page 7, line 17. Preferred topical formulations are described as comprising a safe and effective amount of azithromycin and a pharmaceutically acceptable topical oral carrier. The types of formulations contemplated by Kornman, however, are dentifrices, toothpastes, mouthwashes, mouth rinses, and dental rinses, chewing gum, and lozenge carriers, formulations which are clearly inappropriate for topical application to an eye. In fact, for the topical carrier useful in Kornman's topical formulations, Kornman refers the reader to US patents 4,994,262 and 4,990,329, a copy of each patent being included herewith as Exhibit A and Exhibit B, respectively. Both patents describe conventional formulations such as toothpaste or tooth powder or liquid formulations which can contain relatively large amounts of alcohol (e.g., ethanol). These formulations are inappropriate and perhaps dangerous if applied directly to an eye. Formulations such as toothpastes contain high amounts of solids comprising abrasive cleansing agents, such as calcium carbonate, calcium phosphates, sodium metaphosphate, silicas, and aluminas, making such formulations incompatible with the ocular surface because of the potential for causing irritation and/or injury. Furthermore, the viscosity of these formulations is not generally suitable for application to the eye. Mouth rinses and washes contain high concentrations of organic solvents, including alcohol, and are not tolerated in the eye. Lozenges, chewing gum, and the like, are simply not dosage forms associated with topical application for the eye. Thus the Kornman reference, read in context and including the supporting publications it cites, does not disclose formulations for topical application to an eye. Applicant's topical eye formulation is clearly

nonobvious over the oral cavity-treating disclosure of Kornman, and it is respectfully requested that the rejection be withdrawn.

In summary, although semisolid dosage forms, such as gels, ointments and creams are vehicles which may be used for delivering drugs to the eye and the oral cavity, the compositional requirements for topical eye formulations and oral cavity formulations are fundamentally different, as supported by Kornman, the cited reference and the references cited therein. Hence, gels, ointments and creams formulated for treating diseases of the oral cavity are generally not suitable for topical application to the eye.

The Examiner's comment that claim 7 would be allowable if rewritten in independent form is noted, again with gratitude. It is respectfully submitted, however, that all intervening claims are allowable based on the traversal presented herein, and Applicants elect to defer further amendment until the Examiner has considered the aforementioned traversal.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

Date: AUGUST 5, 2002

James T. Jones
Attorney for Applicant
Reg. No. 30,561

Pfizer Inc
Patent Department
Eastern Point Road
Groton, CT 06340
(860) 441-4903